The Time Out Procedure: have we changed our practice?

Alex J-J Lee, Sumit Raniga, Gary Hooper, Ali Perry, Robyn Bisset, Diane Darley, Carmel Hurley-Watts

Abstract

Background A preoperative surgical safety checklist was implemented into three major hospitals performing elective operations in Christchurch (New Zealand) in 2004. A prospective analysis of the results of this “Time Out Procedure” (TOP) was performed upon its implementation and 4 years later.

Methods All members of the surgical team who participated in the TOP were recorded, as were the details of any discrepancies encountered during the TOP. The results of the initial prospective analysis from September 2004 until April 2005 (Phase 1, 10330 procedures) were compared to a further prospective study 4 years later from October 2008 until September 2009 (Phase 2, 25086 procedures). Surgeons’ attitudes towards the TOP were analysed with a questionnaire.

Results There were no wrong site operations in either phases of the study. Completion of the TOP improved in Phase 2 (98% compared to 87%, p<0.001). The overall discrepancies observed increased, (7.7% in Phase 1 and 9.3% in Phase 2, p<0.001) with surgeon being absent at the TOP resulting in 73% of the discrepancies observed. Only 86% of surgeons believed that TOP was valuable in reducing wrong site operation.

Conclusion This study suggests that surgical checklists such as the TOP are a useful tool in identification and prevention of wrong site surgery. Our practice with consent and limb marking has improved over the two study periods. However, there continues to be surgeon resistance to these checklists, and further research will help to identify the reasons and possible solutions to this phenomenon.

Data suggests that nearly half of all adverse events in hospitalised patients are related to surgical care, and significantly, at least half of these may be preventable. Implementation of a simple, widely applicable and measureable system that may prevent these critical events has been the focus of a widely publicised campaign by the World Health Organization (WHO).

The WHO “Safe Surgery Saves Lives” campaign in 2008 led to the introduction of the WHO Surgical Safety Checklist to operating theatres around the world. Implementation of this tool has been shown to reduce the mortality and inpatient complications from a baseline of 1.5% and 11%, to 0.8% and 7% respectively. In a prospective analysis of elective surgical procedures, the use of a surgical checklist has been shown to detect significant errors or prevent critical events from occurring in 7.7% of all operations.
In New Zealand, District Health Boards reported that, for the 2009/10 year, 374 people treated in their hospitals were involved in a serious or sentinel adverse clinical event that was actually or potentially preventable.\textsuperscript{5}

Adverse medical events are not only devastating for the patients, their families and the health professionals involved but place a significant burden on health expenditure, accounting for 20% (NZ$600 Million) of health spending in New Zealand.\textsuperscript{5}

Recent media reports have highlighted some of the issues around the implementation of the WHO surgical safety checklist in New Zealand, with less than half of New Zealand District Health Boards utilising the WHO Surgical safety checklist.\textsuperscript{6}
Comparatively, in the United Kingdom, the WHO surgical safety checklist has been made mandatory in all National Health Service hospitals despite the various disadvantages and issues related to its successful implementation in the literature. In the WHO pilot study over 90% of clinicians said they would want the checklist to be used if they needed surgery.\(^7\)

In 2006, Pronovost et al\(^8\) successfully implemented a simple checklist for central venous catheter insertion in the intensive care unit, with the aim to ensure evidence-based guidelines were followed to minimise central venous line infections.

A preoperative surgical safety checklist, similar in design to Pronovost’s checklist, with a specific focus on the preoperative safety was implemented into the three major elective surgery hospitals in Christchurch in 2004. It was called the ‘‘Time Out Procedure’’ (TOP) and was carried out immediately after induction of anaesthesia and prior to preparation and draping of the surgical site (Figure 1).

The aim of this study was to prospectively analyse the results of such a checklist by comparing the initial results of implementation of the TOP to the results 4 years later. We wished to compare the discrepancies in the checklist to see whether the accuracy of the documentation, initiation and acceptance of the TOP had improved and to determine whether surgical practice had changed as a result.

**Methods**

The TOP was implemented into the three major hospitals performing elective operations in Christchurch (New Zealand) in 2004 and was performed in all surgical specialties.

The TOP involved a circulating nurse calling “Time Out”, ensuring that all members of the surgical team, including surgeons and their assistants, anaesthetists, anaesthetic technicians and all nursing staff were in attention.

Once the attention of all members of the surgical team was ensured, the pertinent patient identification information was then read from the completed surgical consent form, followed by the proposed surgical procedure and site/side of operation. This information was then crosschecked by other members of the surgical team against the patient’s identification label, as well as patient clinical documentation, and appropriate surgical site marking was confirmed prior to proceeding with surgical site preparation and draping.

The completed TOP sheets were collected by the respective theatre managers, and then collated and analysed on a monthly basis. Any discrepancy from the TOP form was categorised as:

- **System or Process Discrepancy** which included non participation of the surgical team or incorrect timing of the TOP.
- **Consent and Limb Marking Discrepancy** including incorrect consent, wrong limb/site marked or no marking.
- **Incorrect Patient Details**.
- **Critical or Near Miss Events**.

These discrepancies were collated and analysed.

The initial prospective analysis was completed shortly after the implementation of the TOP, from September 2004 until April 2005 (Phase 1). A further prospective study was performed 4 years later from October 2008 until September 2009 (Phase 2).

A questionnaire was then designed to examine the consultant surgeons’ attitudes towards the TOP. One statement that we felt most likely to be relevant was modified from the Safety Attitudes Questionnaire, which is a validated instrument used to measure attitudes in various safety-related domains in healthcare.\(^9,10\) This statement was ‘‘The Time Out Procedure is a valuable tool in preventing wrong site surgery.’’
Four more statements were developed to address the utility of the time out procedure, as well as the role of the surgeon and the surgical team in preventing wrong site operation. To maximise response rates, objective questions were answered first, and statements regarding the surgeons’ own behaviours were answered last.

All responses were marked as ‘agree’, ‘not sure’, and ‘disagree’. A pilot study was performed on three consultant surgeons, using a convenience sample, from which we did not identify any problems.

A total of 53 questionnaires were hand delivered to the respective departmental secretaries of the all surgical specialties in Christchurch Public Hospital. All questionnaires were accompanied by sealable return envelopes to maintain anonymity. We did not record any identifying data. The responses were then collated and analysed.

Intervention: During the 4 years, the continuation of the TOP was ensured by the respective operating theatre managers, and all operating theatre nurses, including newly employed staff, received continual training on its implementation.

Primary outcome: Changes in the rate of discrepancies between the two study phases, plus surgeons attitudes toward the TOP and its roles after 4 years of experience.

Statistical analysis was performed with OpenEpi (v2.3.1) software. The level of significance (two-tailed) was set at \( p<0.05 \). The Mantel-Haenszel Chi-squared test was utilised to compare Phase 1 to Phase 2. Data collection in both study phases was performed at the same hospitals, and therefore it was assumed that the two data sets came from distributions with similar discrepancies.

This study was approved by the Upper South A Regional Ethics Committee of the Ministry of Health.

Results

There were no wrong site operations during the 8 months (Phase 1) and 12 months (Phase 2) of data collection.

The comparison of the total number of operative procedures and completed TOP forms between Phase 1 and Phase 2 is shown in Table 1.

### Table 1. Comparison of total operations and Time Out Procedures (TOP) between Phase 1 and Phase 2

<table>
<thead>
<tr>
<th>Time Out Procedure</th>
<th>Phase 1</th>
<th>Phase 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total operations</td>
<td>10330</td>
<td>25086</td>
</tr>
<tr>
<td>Incomplete TOP</td>
<td>1321 (12.8%)</td>
<td>434 (1.7%)</td>
</tr>
<tr>
<td>Completed TOP</td>
<td>9009 (87.2%)</td>
<td>24652 (98.2%)</td>
</tr>
<tr>
<td>Total incidents</td>
<td>695 (7.7%)</td>
<td>2281 (9.3%)</td>
</tr>
</tbody>
</table>

There was a significant improvement in completing the TOP forms with 98.2% completed in Phase 2 compared to the earlier Phase 1 (87.2%, \( p<0.001 \)) but there was a higher rate of total incidents in Phase 2 (9.3% compared to 7.7%, \( p<0.001 \)). The TOP was not performed in 24 out of 434 Incomplete TOPs in Phase 2.

The discrepancies are summarised in Table 2. System and process discrepancy was the major contributor, with Phase 2 having 73.6% errors compared to Phase 1 (29.7%, \( p<0.001 \)). The great majority of these were due to absence of the surgeon and/or the assistant at the TOP.
Consent and limb marking discrepancies had improved in Phase 2 (25% compared to 38%; p<0.001) with some improvement in the accuracy of the consent, however there remained a high incidence of no site marking (7.1%).

There was a significant increase in no site/side documentation on the surgical consent or operation list in Phase 2 (4% compared to 1.4%; p<0.001). While site/side variation between the consent form, operating list or patient notes had improved to 3.9% in Phase 2 compared to 11.7% in Phase 1.

Accuracy of patient information had improved by Phase 2 (1.4% compared to 4.2%, p<0.001) however there were still 31 procedures performed where the patient details were incorrect to the point that the patient would not have been able to have a blood transfusion on the preoperative cross-match or group and hold.

There were three ‘near misses’ in Phase 1 which were captured by the TOP. Two of these involved changes in the order of the list, and subsequently, the wrong patient was present in the operating room. One case involved a surgeon having a different understanding as to what surgical procedure was going to be performed compared to that written on the consent form. There were no ‘near misses’ in Phase 2.

It was noted that 4 surgeons refused to be involved in the TOP in Phase 1 as they felt they had already checked the site or side, or thought that the TOP was too time consuming.

### Table 2. Comparison of Time Out Procedure discrepancies between Phase 1 and Phase 2

<table>
<thead>
<tr>
<th>Time Out Procedure discrepancies</th>
<th>Phase 1</th>
<th>Phase 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>System/Process Discrepancy</td>
<td>206 (29.7%)</td>
<td>1679 (73.6%)</td>
</tr>
<tr>
<td>Surgeon/Assistant Not Present*</td>
<td>129 (18.6%)</td>
<td>1665 (73%)</td>
</tr>
<tr>
<td>TOP Post Preparation &amp; Draping</td>
<td>35 (5%)</td>
<td>14 (0.6%)</td>
</tr>
<tr>
<td>Consent/Limb Marking Discrepancy</td>
<td>265 (38%)</td>
<td>571 (25%)</td>
</tr>
<tr>
<td>Operation Side/Site Not Marked</td>
<td>75 (10.8%)</td>
<td>162 (7.1%)</td>
</tr>
<tr>
<td>No Site/Side Documentation *</td>
<td>10 (1.4%)</td>
<td>91 (4%)</td>
</tr>
<tr>
<td>Site/Side Variation *</td>
<td>81 (11.7%)</td>
<td>89 (3.9%)</td>
</tr>
<tr>
<td>Alterations/Additional Procedures*</td>
<td>44 (6.3%)</td>
<td>229 (10%)</td>
</tr>
<tr>
<td>Incorrect Patient Details*</td>
<td>29 (4.2%)</td>
<td>31 (1.4%)</td>
</tr>
<tr>
<td>Critical/Near Miss Events*</td>
<td>3 (0.4%)</td>
<td>0</td>
</tr>
</tbody>
</table>

*Indicates where significant difference was found between Phase 1 and Phase 2.
Fifty-three questionnaires examining the attitudes of consultant surgeons towards the Time Out Procedure were distributed and 50 completed questionnaires were received with a 94% response rate (Table 3).

The majority of the consultant surgeons agreed that wrong site operation was a devastating but preventable complication with only one disagreeing. Most (88%) of the surgeons agreed that the time out procedure is a valuable tool in preventing wrong site operation, while five were ‘not sure’ and one disagreed.

There was general agreement that all members of the surgical team have a collective responsibility in ‘getting it right’, and that surgeon participation in the time out procedure was vital to its success and should be mandatory.

### Table 3. Time Out Procedures consultant questionnaire results

<table>
<thead>
<tr>
<th>Time Out Procedure questionnaire</th>
<th>Agree</th>
<th>Not sure</th>
<th>Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrong site operation is a devastating but preventable complication.</td>
<td>98% (49)</td>
<td>0</td>
<td>2% (1)</td>
</tr>
<tr>
<td>The Time Out Procedure is a valuable tool in preventing wrong site operation.</td>
<td>88% (44)</td>
<td>10% (5)</td>
<td>2% (1)</td>
</tr>
<tr>
<td>All members of the surgical team have a collective responsibility in ‘getting it right’.</td>
<td>94% (47)</td>
<td>2% (1)</td>
<td>4% (2)</td>
</tr>
<tr>
<td>Surgeon participation in the Time Out Procedure is vital to its success and should be mandatory.</td>
<td>92% (46)</td>
<td>6% (3)</td>
<td>2% (1)</td>
</tr>
<tr>
<td>I believe that the Time out procedure is a valuable and integral part of the surgical procedure.</td>
<td>86% (43)</td>
<td>10% (5)</td>
<td>4% (2)</td>
</tr>
</tbody>
</table>

### Discussion

The final responsibility of avoiding wrong side/site operation rests with the surgical team and all necessary procedures should be performed to achieve this goal. The Joint Commission on Accreditation of Health Care Organizations advocated the use of the TOP as a final check and verification of patient’s details prior to any invasive procedure and this recommendation has been adopted by many health care organisations and hospitals within the USA. Recent WHO guidelines have been introduced in many hospitals to not only decrease wrong site operation but also to improve patient outcomes by decreasing perioperative and postoperative complications. However, Operating Room (OR) processes and procedures can be difficult to change.

The initial Phase 1 of this study reported four surgeons who did not want to change their surgical practice as they considered that they had already checked the appropriate side/site. After 5 years this attitude had not changed, with only a proportion of surgeons agreeing that the TOP was a valuable tool in preventing wrong
site operation and believing that it was a valuable and integral part of the surgical procedure.

This surgeon indifference to TOP is hard to understand when National and International agencies have stressed the value of such a surgical check list and its role in prevention of surgical errors.

Others have reported similar compliance results with only 92% satisfactory site identification from either site signing or ‘Time Out’ despite adopting the Joint Commission on Accreditation of Healthcare Organisations recommendations as a mandatory requirement.12

This study has been valuable in showing that the changes in OR practice over a period of 5 years from the start of a formal safety check has resulted in a significantly higher completion of the TOP. The TOP continued to be a useful tool in identifying discrepancies and preventing potentially devastating errors.

There was a higher rate of discrepancies in Phase 2 of the study, mostly contributed by the surgeons not being present at the initiation of the TOP. This may reflect improvements in the overall implementation of the TOP, but perhaps stronger emphasis is needed on the importance of the team approach in ‘getting it right’, which includes the surgeons. This will enable such checklists to improve teamwork, communication, and attitudes toward quality and safety, as demonstrated by a number of studies.3,13–15

Despite the majority of surgeons agreeing that “surgeon participation in the Time Out Procedure is vital to its success and should be mandatory”, this continued to be the largest discrepancy in Phase 2 where an absent surgeon at the time of TOP contributed to a significant proportion of the variances observed. Koshbin et al15 have reported similar failures in compliance, where absence of surgeon at the time-out contributed to 35.1% of discrepancies.

Interestingly, the completion rate for time-out was also similar to our study (99.1%). This supports our belief that emphasis on the correct implementation of the TOP is needed, and the TOP must not be considered as a ‘lip-service’ activity. Some argue that culture barriers between the profession of surgery, nursing and anaesthesia may hinder the correct uptake of such checklists.16 Each profession is used to working independently, with their own priorities in the OR. This may explain, to some extent, why the TOP was initiated in the absence of the surgeons.

Amalberti et al.17 argues that “historical and cultural precedents and beliefs that are linked to performance and autonomy,” pose the greatest threat to improved safety.

There were 24 procedures in Phase 2 where TOP was not performed which could have been avoided by having a specific person in each OR designated to initiate the TOP. However, even with this mechanism in place, it seems obvious that the reliability of completing TOP will not improve until there is complete ‘buy-in’ from the surgeon.

The area of Consent had improved over the 5 years with far fewer incorrect consent forms. However there still remains a significant concern over the number of sites that were not marked, those with no site/side documentation on the surgical consent or
operation list, and site/side variation between the consent form, operating list or patient notes.

Site marking has become mandatory in several countries and is considered to be the most important means to prevent wrong site operation. Some specialties felt that it was unnecessary to mark the site as they felt it was obvious which side/site was being operated on. Our questionnaire was anonymous and therefore we could not make any comparisons between specialties and the completion of TOP.

Although there were three ‘critical events’ in Phase 1 of the study, where the potential for a significant error occurred, there were no such events in Phase 2. This improvement supports the use of the TOP and increased awareness by the whole surgical team.

There are several limitations of this study. There has not been any analysis of the incidence of discrepancies prior to the introduction of the TOP, thus we are unable to make any definitive conclusions regarding the overall effectiveness of the TOP. However, it seems obvious that such a checklist would be an effective tool in minimising adverse outcomes in the surgical patients, as shown by the three critical/near miss events in Phase 1.

Additionally, a significant focus of the WHO process was an overall improvement in morbidity considered to be related to improving the teamwork aspects in the operating theatre. No outcome analysis of perioperative morbidity and mortality has been done in this study, thus it is difficult to make direct comparisons between the TOP and the WHO checklist.

The data collection period was longer in Phase 2 of the study by 4 months. Subsequently, a large difference was observed in the number of TOP analysed, and direct comparison of results between the two phases was made difficult. However, throughout the year, there were no significant differences in the overall case mix across the three hospitals, and in the pattern of employment of personnel responsible for implementing the TOP, making it unlikely that seasonal effects would contribute to the differences observed between the two phases.

There are potential limitations in the questionnaire design. The first statement contains a double question, and it is difficult to ascertain whether one is disagreeing to all or part of the question. Furthermore, the pilot study was not representative of all surgical specialties. However, attempting to obtain a representative sample seemed impractical as some specialties have significantly lower number of surgeons than others.

Finally, some surgeons may have been involved in a larger quality improvement initiative in the hospital, and this may have influenced their responses to demonstrate the success of the initiative. This source of bias could not be excluded.

As evident from Phase 1 of the study, some surgeons may perceive the TOP as an unnecessary time consuming activity, and only exposed members of the surgical team if a problem occurred. However, we believe that the introduction of this procedure has had the reverse effect where the surgical team has accepted collective responsibility for ‘getting it right’. This has generally resulted in an improved and successful
relationship between hospitals (both public and private), operating rooms and professional groups (surgeons, anaesthetists, nurses and anaesthetic technicians).

The WHO checklist, which was introduced nationally in New Zealand in 2010 and made a mandatory process by the Ministry of Health, is a much more comprehensive preoperative check compared to TOP. It includes questions about treatment (antibiotic and anti-thromboembolic prophylaxis) and potential surgical and anaesthetic problems.

This expanded checklist may improve compliance and decrease the discrepancies that we have exposed in this study. However, given that there is persistent incompliance with the TOP since its implementation, one must question how well the more complicated WHO checklist has been incorporated into our practice. However, the comprehensive nature of the WHO checklist provides a more standardised process which improves interdisciplinary communication.

This promotes teamwork and creates a safety culture, which empowers all team members to speak up about potential errors and become more proactive about patient safety\textsuperscript{18,19}. If this culture of safety is properly instilled into the OR, it may in fact, improve compliance.

**Conclusion**

This study suggests that surgical checklists such as the TOP are a useful tool in identification and prevention of wrong site surgery. Consent and limb marking practice have improved over the two study periods. Despite the apparent benefits, there continues to be resistance to these checklists by some surgeons, and further research will help to identify the reasons and possible solutions to this phenomenon.

**Competing interests:** None known.

**Author information:** Alex J-J Lee, House Officer, Department of Orthopaedic Surgery, Christchurch Hospital, Christchurch; Sumit Raniga, Orthopaedic Trainee, Department of Orthopaedic Surgery, Christchurch Hospital, Christchurch; Gary J Hooper, Senior Lecturer, Orthopaedic Surgeon, Department of Orthopaedic Surgery and Musculoskeletal Medicine, University of Otago, Christchurch; Ali Perry, Operating Theatre Manager, St Georges Hospital, Christchurch; Robyn Bisset, Day Surgery Unit Manager, St Georges Hospital, Christchurch; Diane Darley, Nurse Manager, Operating Suite, Burwood Hospital, Christchurch; Carmel Hurley-Watts, Theatre Services Manager, Southern Cross Hospital, Christchurch

**Correspondence:** Dr Alex J-J Lee, Department of Orthopaedic Surgery, Christchurch Hospital, Riccarton Avenue, Private Bag 4710, Christchurch 8011, New Zealand. Fax: +64 (0)3 3640909; email: jaejinl.lee@cdhb.govt.nz

**References:**